UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/935,344	08/23/2001	Vic Jira	22220-00003-US	8106

30678 7590 02/12/2008

CONNOLLY BOVE LODGE & HUTZ LLP
1875 EYE STREET, N.W.
SUITE 1100
WASHINGTON, DC 20036

EXAMINER	
LUCAS, ZACHARIAH	

ART UNIT	PAPER NUMBER
1648	

MAIL DATE	DELIVERY MODE
02/12/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/935,344	JIRA ET AL.	
	Examiner	Art Unit	
	ZACHARIAH LUCAS	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 December 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3 and 5-16* is/are pending in the application.

4a) Of the above claim(s) *10-12* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,5-9 and 13-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1, 3, and 5-16 are pending in the application.

2. In the prior action, mailed on June 19, 2007, claims 1, 3, and 5-16 were pending in the application, with claims 1, 3, 5-9, and 13-16 under consideration and rejected, and claims 10-12 withdrawn as to non-elected inventions.

3. In the Response of December 19, 2007, the Applicant amended claims 1, 3, and 5.

4. Claims 1, 3, 5-9, and 13-16 are under consideration.

Claim Rejections - 35 USC § 112

5. **(Prior Rejection- Withdrawn)** Claim 1 was rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This claim reads on a multivalent antiviral vaccine comprising "one or more" antigens. In view of the deletion of the "multivalent" requirement, the rejection is withdrawn.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. **(Prior Rejection- Maintained)** Claims 1, 3, 5-9, and 13-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meruelo (U.S. 5,506,271) further in view of either of Felici et al. (U.S. 5,994,083), or Ooyama et al. (EP 0 775 494), and further in view of the teachings of Rios et al. (U.S. 6,383,806) and Lathe et al. (U.S. 6,024,953). The claims have been amended to require that the compositions are denatured at a temperature of higher than about 110° C.

The Applicant traverses the rejection on two grounds.

First, the Applicant asserts that none of the references teaches the denaturation of the cells. This argument is not found persuasive as the rejection clearly indicated that this was the case, and made the rejection not because the references teach the denaturation of the cells, but because it would have been obvious to those of ordinary skill in the art to have applied the process of Meruelo to the compositions suggested by Rios or Lathe so as to make compositions comprising denatured antigens and virus infected cells. In view of the teachings of Meruelo that heat denaturation is an alternative to chemical inactivation treatments, the Applicant's arguments are not found persuasive.

With respect to the amendment of the claims to require that the antigens are denatured at a temperature of greater than about 110 ° C, it is noted that there has been no showing that the currently claimed temperature range is critical to the claimed invention. Moreover, the teachings of Meruelo indicate that the temperature used may be increased, when accompanied by a similar decrease in treatment period. See e.g., column 12, lines 47-49. Thus, it would have been obvious to those of ordinary skill in the art to have adjusted the temperature of the treatment to optimize

performance. The claimed method is therefore obvious as it would have been characterized during the course of routine optimization.

For the reasons above, and the reasons of record, the rejection is maintained.

8. **(Prior Rejection- Maintained)** Claims 5-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamamoto (U.S. 6,544,528) in view of Meruelo (U.S. 5,506,271) and further in view of either of Felici et al. (U.S. 5,994,083), or Ooyama et al. (EP 0 775 494). The claims have been amended as indicated above.

The Applicant asserts that the Yamamoto reference does not teach the denaturation of cells. Nonetheless, as the cells are being heat treated and as heat causes denaturation, the Applicant's arguments are not found persuasive.

With respect to the assertion that none of the references teach the conditions for denaturation as claimed in the present application; this argument is not found persuasive in view of the teachings of Meruelo for the reasons indicated above (i.e. the optimization of the method described by that reference).

With respect to Applicant's (unsupported) assertion regarding "dry denaturation," it is noted that the claims nowhere refer to such a technique. Rather, the read on a dry immunogen that has been denatured. Such a composition is suggested by the teachings of the art as described previously and above. This argument is therefore also not found persuasive.

For the reasons above, and the reasons of record, the rejection is maintained.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Conclusion

10. No claims are allowed.

11. The following prior art references are made of record and considered pertinent to applicant's disclosure. However, while relevant they are also not used as a basis for rejection for the stated reasons.

> Yoshizawa et al., JP 57175127 (English abstract attached). This reference also teaches heat-inactivated antigens, heated at 60° for 10 hours. The teachings of this reference are cited as close prior art.

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ZACHARIAH LUCAS whose telephone number is (571)272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Zachariah Lucas/
Primary Examiner, Art Unit 1648